

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                           |                          |
|---------------------------|--------------------------|
| In re Application of:.    | §                        |
|                           | §                        |
| Lola WEISS et al          | §                        |
|                           | § Confirmation No.: 3826 |
| Serial No.: 10/589,623    | §                        |
|                           | §                        |
| Filed: August 16, 2006    | § Group Art Unit: 1628   |
|                           | §                        |
| For: TREATING OR          | §                        |
| PREVENTING DIABETES       | §                        |
| WITH CANNABIDIOL          | §                        |
|                           | § Attorney Docket: 32361 |
| Examiner: Jennifer M. KIM | §                        |

**DECLARATION OF RUTH GALLILY UNDER 37 CFR 1.132**

I am presently employed as researcher at the Lautenberg Center of Immunology the Hebrew University-Hadassah medical school, Jerusalem, where I am a a Emeritus professor. I received my Ph.D degree from the Hebrew University in 1956, worked as a post-doctoral fellow in Sloan-Kettering Institute, NY, USA; Research Associate in Johns Hopkins University Baltimore USA; California Institute of Technology, USA and was a visiting Professor at UCLA and UCSF, CA ,USA

My research focuses mainly on Immune mechanism, especially on Innate immunity. Since the beginning of my career, I have published 154 scientific articles in highly regarded journals and books, and have presented my achievements at many international scientific conferences.

I am a member of Society of Sigma Xi, CIT Chapter; Israel Immunology Society; Society of Leukocyte Biology (Honorary Life membership); International Cytokine Society; and International Cannabinoid Society, was awarded Honorary Life Membership of the Society for Leukocyte Biology and life Membership in John Hopkins Society for Scholars.

I am a co-inventor of the subject matter claimed in the above-referenced U.S. patent application.

I have read the Official actions issued with respect to the above-identified application.

In this official action the Examiner has rejected claims 1-5, 8-10, 24 and 26 under 35 U.S.C 103, as being unpatentable over R&D Profile of record (2003) in view of Spevak (7,071,231) and Gorter (1999).

The Examiner specifically states that R&D profile teaches the D9 THC and CBD have been employed in a clinical trial of peripheral neuropathy secondary to diabetes mellitus. Spevak et al. teach that Type II is the most prevalent form of diabetes and Gorter teaches that CBD antagonizes the psychotropic actions of THC. Therefore the skilled in the art would use the composition described in the R&D profile for the treatment of T2DM given the excellent safety data and the absence of psychotropic activity as taught by Gorter.

Being an expert in the field of CBD and cannabis-based medicine, as evidenced by the attached list of publications in peer reviewed journals, I hereby declare that the THC:CBD composition employed in the R&D profile publication, is characterized by psychotropic activity.

In evidence to that I refer the Examiner to:

1. the R&D profile publication showing that the THC:CBD composition was registered as Sativex<sup>R</sup>. See Table II page 309 of the R&D Profile. XXX-THIS IS THE WEAKEST POINT

2. the substrate product characteristics (SPC, attached herewith) of Sativex published by GWPharmaceuticals showing that Sativex has psychotropic effects.

Psychiatric symptoms such as anxiety, illusions, changes in mood, and paranoid ideas have been reported during treatment with Sativex. These are likely to be the result of transient CNS effects and are generally mild to moderate in severity and well tolerated. They can be expected to remit on reduction or interruption of Sativex medication.

In view of the above, it is my expert opinion that the compound disclosed by the R&D profile publication is psychoactive and therefore can't be used to anticipate or render obvious the claimed invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United states Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

July 12, 2011

*Ruth Gallily*

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Prof. Ruth Gallily  
Lautenberg Center of Immunology, the Hebrew University  
Israel

***Enc.:***

CV of Prof. Gallily and List of publications  
Sativex SPC

**Ruth Gallily**  
**CURRICULUM VITAE**

|   |  |
|---|--|
| <b><u>Citizenship:</u></b>                          | Israeli  |
| <b><u>Family Status:</u></b>                        | Widow, 3 children  |
| <b><u>Military Service:</u></b>                     | 1947 – 1948: War of Independence   |
| <b><u>Education:</u></b>                            |  |
| 1957-1958   | Postdoctoral Research Associate, Dept. of Biochemistry, University of Illinois, Urbana, Illinois                                 |
| 1956-57   | Postdoctoral Research Associate, Sloan Kettering Institute, New York   |
| 1956  | Ph.D. The Hebrew University of Jerusalem and Weizmann Institute of Science, Rehovot<br>Thesis: Genetics of Tumor Transplantation |
| 1952  | M.Sc. in Biology & Biochemistry, Hebrew University of Jerusalem  |
| 1945  | Reali High School  |
| <b><u>Employment:</u></b>                           |  |
| 1995-present  | Professor Emeritus   |
| 1993 (3 months)                                     | Visiting Professor; Dept. of Radiation Therapy, The Sloan Kettering Institute, New York  |
| 1993 (3 months)                                     | Short-term member of Wolfson College, Oxford and Dunn School of Pathology; Oxford, England                                       |
| 1989-1990   | Visiting Professor, Dept. of Cell Physiology and Immunology, The Rockefeller University, New York                                |
| 1982-1983   | Visiting Professor, Department of Microbiology and Immunology UCSF, San Francisco, California                                    |
| 1979-present  | Professor of Immunology, Lautenberg Center   |
| 1979  | Visiting Investigator, Sloan-Kettering Institute, New York   |
| 1977-1978   | Visiting Associate Professor, Department of Microbiology and Immunology, UCLA, Los Angeles, California                           |
| 1976-1979   | Associate Professor, Department of Immunology, Hebrew University of Jerusalem  |
| 1971-1976   | Senior Lecturer, Department of Immunology, Hebrew University of Jerusalem  |
| 1967-1969   | Research Fellow, Immunochemistry, California Institute of Technology, Pasadena, California                                       |
| 1964-1967   | Research Associate, Department of Cell Biology, Weizmann Institute of Science, Rehovot   |
| 1962-1964   | Research Associate, School of Hygiene and Public Health, Johns Hopkins University, Maryland                                      |
| 1959-1962   | Research Associate, Weizmann Institute of Science, Rehovot   |
| <b><u>Honors</u></b>                                |  |
| 1995  | Life-time Membership in Johns Hopkins Society for Scholars   |
| 1992  | Honorary Life Membership of the Society for Leukocyte Biology  |
| <b><u>Membership in Professional Societies:</u></b> |  |
|   | Society of Sigma Xi, CIT Chapter   |
|   | Israel Immunological Society   |
|   | Society of Leukocyte Biology (Honorary Life Membership)  |
|   | European Reticuloendothelial Society (EURES)   |
|   | European Association for Cancer Research   |
|   | International Cytokine Society (ICS)   |
|   | International Cannabinoid Society (ICRS)   |